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510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety and Effectiveness for the EBI® XFIX® DFS® System is provided as required per Section 513(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** EBI, L.P.
100 Interpace Parkway
Parsippany, NJ 07054

Contact Person: Frederic Testa
Telephone: (973) 299-9300

Date prepared: December 26, 2001

2. **Proprietary Name:** EBI® XFIX® DFS® System

Common Name: External Fixation Device

Classification Names: Single/Multiple Component Metallic Bone Fixation

Appliances and Accessories, 21 CFR 888.3030

3. **Predicate or legally marketed devices that are substantially equivalent:**

- EBI® XFIX® DFS® System – EBI, L.P. (K953406)

4. **Description of the device**. The system consists of external fixation components and implantable bone screws. The EBI® XFIX® DFS® System is utilized in the following manner: bone screws are inserted through the patient's skin and soft tissue and into the bone. This submission is for a labeling change to reflect that the **EBI® XFIX® DFS® Standard Fixator** may be reused twice when the Central Body Component is replaced between each reuse.

3. **Intended Use:** The EBI® XFIX® DFS® System is intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis,

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fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality.

4. **Materials:** The components of the System may be manufactured from materials such as titanium, stainless steel, and aluminum.

5. **Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between the EBI® XFIX® DFS® System and other currently marketed external fixation systems. It is substantially equivalent* to the predicate devices in regards to intended use, materials, and function.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2002

EBI
Jon Caparotta, RAC
Manager, Regulatory Affairs 7 Studebaker
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K014276
Trade Name: XFIX® DFS® System
Regulation Number: 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: II
Product Code: KTT
Dated: January 30, 2002
Received: January 31, 2002

Dear Mr. Caparotta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K014276

Device Name: EBI® XFIX® DFS® System

Indications For Use:

The EBI® XFIX® DFS® System is a unilateral external fixation device intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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